electronic meter. Other expensive but accurate and non-invasive products are being developed largely for Type 1 diabetics including techniques such as infra-red scanning. Less accurate urine tests are available for Type 2 diabetics. Because of the nature of current diagnostics, Type 2 diabetics do not test themselves very often. Hence, there is a market need for Type 2 diabetics to test themselves with an inexpensive, qualitative, non-invasive product. The assay tests of the present invention meet these needs.

In some embodiments of the present invention, the glucose test assay is a qualitative assay, indicating the presence of glucose at or above a particular threshold level. Qualitative assays find use by diabetics in monitoring glucose levels, wherein the information is used in making dietary and/or medical decisions. In other embodiments, the glucose test assay is a quantitative assay, wherein a particular concentration of glucose is determined.

Glucose assay tests of the present invention may be used with the delivery systems of the present invention, provide durability, improved shelf-life, and ease-of-use.

The non-toxic, non-irritant, non-carcinogenic reactions means discussed above for alcohol detection finds use in the glucose assay tests. Glucose oxidase is supplied in place of alcohol oxidase. Glucose oxidase reacts with glucose present in the saliva sample to generate gluconic acid and hydrogen peroxide. The hydrogen peroxide, like that in the alcohol detection assay, stimulates a color response. Thus, in some preferred embodiments, the present invention provides a glucose assay test comprising glucose oxidase and a non-toxic chromogen (e.g., potassium iodide). In other embodiments, the reaction means comprises hexokinase which reacts with glucose to form glucose-6-phosphate with the concomitant conversion of $NADP^+$ to NADPH. The $NADP^+$/NADPH conversion may be coupled to a color detection system (See e.g., U.S. Pat. Nos. 5,032,506 and 5,036,000, herein incorporated by reference in their entireties). In preferred embodiments, the reaction means containing the oxidase and chromogen is present in a reactive pad on the end of a test strip, wherein the pad is placed directly in the mouth. Additional systems, chemistries, and detection modes for

carrying out glucose detection are described in U.S. Pat. Nos. 6,102,872, 3,964,871, 5,217,691, 5,140,985, 6,194,224, 5,179,288, 5,714,341, 5,989,917, 4,476,222, and 5,912,139, herein incorporated by reference in their entireties.

C) Other Assay Tests

1) Prostate-Specific Antigen (PSA)

The present invention provides non-invasive, inexpensive PSA tests. For example, the present invention provides oral PSA tests for monitoring PSA levels from saliva. High PSA levels in saliva correlate with prostate cancer, a noncancerous (benign) enlargement of the prostate (benign prostatic hypertrophy), and infected or injured (trauma) prostate. Every male over the age of 50 in the world should be tested regularly for prostate cancer. Current methods for testing for prostate cancer are two-fold: either an invasive rectal exam or expensive blood work. Because tests are invasive and expensive, many people are not tested regularly, or at all.

In some embodiments of the present invention the reaction means of the assay tests of the present invention contains an anti-PSA antibody (i.e., any immunoglobulin molecule that specifically interacts with PSA or a unique epitope of PSA). The reaction site is placed into the mouth to allow binding free PSA in the saliva to the anti-PSA antibody. The bound complex is then detected using any system of method known in the art. In some embodiments, detection requires the use of a detection apparatus. Systems and methods for PSA detection are described in U.S. Pat. Nos. 5,614,372 and 6,200,765, herein incorporated by reference in their entireties.

2) Ketones

The present invention provides non-invasive, inexpensive ketone tests (i.e., detection of ketone bodies such as acetone, acetoacetic acid and β-hydroxybutyric acid). For example, the present invention provides oral ketone tests for monitoring ketone levels in saliva. Approximately 2.5 million people world-wide are performing diets where ketone levels should be monitored. Also, there are approximately 1-5

million high performance athletes that should regularly measure ketone levels. If dieters' or athletes' ketone levels increase too high, they can go into acidosis and their bodies process muscle tissue instead of fat. The qualitative and/or quantitative measurement of ketone concentrations is important because of the relationship between elevated serum ketone levels and clinical conditions such as diabetes, disorders of the digestive organs, renal insufficiency, uremia and malignant carcinoma. In the course of these disorders, ketone bodies pass into the blood stream and a state of metabolic acidosis (ketosis) occurs. Monitoring for the onset of ketosis is of particular importance in the maintenance of diabetics because the occurrence of ketosis may indicate the need for modification of insulin dosage or other disease management.

The non-toxic, non-irritant, non-carcinogenic reactions means discussed above for alcohol and glucose detection finds use in the ketone assay tests. In some embodiments, the ketone is reacted with enzymes to form oxidized or reduced products (e.g., hydrogen peroxide, $NADP^+$ or NADPH) that can be detected in the systems described above. For example, in some embodiments, the reaction means comprises a dehydrogenase (e.g., 3-hydrocybutric dehydrogenase) which causes $NADP^+$/NADPH conversion (See e.g., U.S. Pat. No. 5,618,686, herein incorporated by reference in its entirety). The $NADP^+$/NADPH conversion may be coupled to a color detection system (See e.g., U.S. Pat. Nos. 5,032,506 and 5,036,000, herein incorporated by reference in their entireties). Additional systems, chemistries, and detection modes for carrying out ketone body detection are described in U.S. Pat. Nos. 3,880,590, 4,440,724, 4,405,721, 4,184,850, 4,097,240, 3,212,855, 4,970,172, and 4,147,514, herein incorporated by reference in their entireties.

Because glucose and ketone levels are both relevant to diabetics, in some embodiments, the present invention provides assay tests that simultaneously detect glucose and ketone levels.

3) Cortisol

The present invention provides non-invasive, inexpensive cortisol tests. For example, the present invention provides oral cortisol tests for monitoring cortisol levels